

K003439

Attachment 1

DEC 15 2000

510(K) SUMMARY

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR §807.92.

Vivant Medical Inc. intends to introduce into commercial distribution the Breast Lesion Localization Device. The equivalent predicate devices are the Homer Mammalok Needle / Wire Localizer (#K852402) by North American Instrument Corporation and the Kopans Breast Lesion Localization Needle by Cook Ob/Gyn Inc.

The FDA has classified sterile disposable devices of this type (CFR 878.4800 -- guide, surgical, instrument) as Class 2 devices. Vivant's Localization Device is a Class 2 medical device. The common name for Vivant's device is a breast localization needle.

The Vivant Breast Lesion Localization Device is intended for the localization of nonpalpable breast lesions. The Homer Mammalok, Kopans, and Vivant localization devices employ a needle cannula which is inserted through the skin of the breast. In all three devices, a wire with a preformed localization element is inserted into the breast tissue via the removable needle cannula. All devices are available in a variety of sizes to meet the various anatomical requirements encountered by the clinician. The device labeling supports the use of these devices in the disciplines of radiology and surgery.

 11/3/00

George Hermann date
Regulatory Affairs
Vivant Medical Inc.
3210B Alpine Rd.
Portola Valley, CA 94028
Phone 650-529-1238



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 15 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Hermann
Regulatory Affairs
Vivant Medical, Inc.
3210B Alpine Road
Portola Valley, California 94028

Re: K003439
Trade Name: Breast Lesion Localization Device
Regulatory Class: II
Product Code: KNW
Dated: November 3, 2000
Received: November 6, 2000

Dear Mr. Hermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

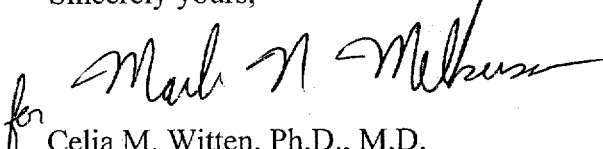
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003439

DEVICE NAME: Breast Lesion Localization Device

INDICATIONS FOR USE:

Localization of nonpalpable breast lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
IF NEEDED.)

f. Mark H. Miller

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003439

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter
(Optional For)